



Amarin Receives Special Protocol Assessment Agreement From The FDA For Phase 3 Trial In Mixed Dyslipidemia

DUBLIN, Ireland, July 9, 2009 – Amarin Corporation plc (NASDAQ: AMRN) today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for its planned Phase 3 clinical trial of AMR101 (ethyl-EPA) in patients with mixed dyslipidemia. Renowned cardiologist and leading expert on dyslipidemia, Dr. Christie Ballantyne, Director of the Center for Cardiovascular Disease Prevention, Methodist DeBakey Heart and Vascular Center, will be the Principal Investigator for this Phase 3 trial.

This is the second SPA agreement received by Amarin for AMR101 in cardiovascular disease and follows the SPA agreement obtained in May 2009 in relation to the planned registration trial with AMR101 in patients with very high triglycerides (the AMR101 MARINE study). The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase 3 trial.

Thomas Lynch, Chairman and Chief Executive Officer of Amarin, commented "Receiving FDA agreement on this Phase 3 trial in mixed dyslipidemia is an important endorsement of our strategy which aims to provide a more comprehensive label for AMR101. We plan to commence both this mixed dyslipidemia trial and the MARINE study in the third quarter of 2009, pending completion of the Company's longer term funding, as described in our press release earlier this week."

Commenting on the upcoming trial, Dr. Christie Ballantyne, Principal Investigator said "I am pleased to be working with Amarin on this trial. There is a very large population of patients with mixed dyslipidemia and elevated triglycerides for whom statins alone are insufficient therapy. AMR101, as an ultra-pure prescription-grade Omega-3 therapy, is particularly promising for combination therapy with statins given the strong safety, tolerability, and efficacy profile of EPA in reducing triglycerides."

The Phase 3 mixed dyslipidemia trial will be a multi-center, placebo-controlled, randomized, double-blind, 12-week study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101 in patients with high triglyceride levels of ≥ 200 mg/dL and < 500 mg/dL who are on statin therapy. The primary endpoint in the trial is the percentage change in triglyceride level from baseline to week 12.

This trial is expected to enroll approximately 650 patients and will be conducted in centers throughout the United States. The Company plans to use the results of this Phase 3 trial as the basis for potentially broadening the label for AMR101 beyond treatment for very high triglycerides to include treatment for high triglycerides, the two patient groups that need hypotriglyceridemic therapy the most, as classified by the National Cholesterol Education Program (NCEP) Expert Panel (Adult Treatment Panel III, ATP III, 2002).

About Dr. Christie Ballantyne

Christie M. Ballantyne, M.D., is Director of the Center for Cardiovascular Disease Prevention, Methodist DeBakey Heart and Vascular Center; Chief of the Section of Atherosclerosis and Vascular Medicine, Interim Chief, Section of Cardiology, Department of Medicine, Baylor College of Medicine; Director of the Maria and Alando J. Ballantyne, M.D., Atherosclerosis Laboratory; Professor of Medicine with a joint appointment in Pediatrics, Baylor College of Medicine; and Co-Director, Lipid Metabolism and Atherosclerosis Clinic, The Methodist Hospital, Houston, Texas. He received his Doctor of Medicine from Baylor College of Medicine, and his postgraduate training included an internal medicine residency at The University of Texas Southwestern Medical School, Dallas, Texas, a cardiology fellowship at Baylor College of Medicine, and an American Heart Association/Bugher Foundation Fellowship at the Howard Hughes Medical Institute and Institute for Molecular Genetics at Baylor. Dr. Ballantyne is a Fellow of the American Association for the Advancement of Science, member of the American Society for Clinical Investigation, Fellow of the American College of Cardiology, and Fellow of the American College of Physicians. He has been a member of numerous steering committees for multicenter trials and is Editorial Director for www.lipidsonline.org. He has published extensively and has spoken nationally and internationally on lipids, atherosclerosis, and inflammation.

About AMR101

AMR101 is an ultra-pure ethyl ester of eicosapentaenoic acid (ethyl-EPA). Amarin has developed a substantial body of data on AMR101 to date. Amarin has previously investigated AMR101 in central nervous system (CNS) disorders in several double-blind, placebo-controlled studies, including Phase 3 trials in Huntington's disease. Over 900 patients have received AMR101 in these studies, with over 100 receiving continuous treatment for one year or more. In all studies performed to date, AMR101 has shown a very good safety profile.

Numerous independent studies have demonstrated the safety, tolerability and efficacy of ethyl-EPA in lowering plasma triglycerides in patients with high triglyceride levels of varying degrees of severity. In Japan, an ethyl-EPA prescription product has been approved for the treatment of hyperlipidemia and has been on the market for over eighteen years.

About Mixed Dyslipidemia

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low high-density lipoprotein (HDL) cholesterol, and elevated low-density lipoprotein (LDL) cholesterol and is believed to affect more than 34 million in the U.S. alone. It is one component of a range of lipid disorders collectively referred to as dyslipidemia. The overall dyslipidemia population in the U.S. is believed to be in excess of 100 million.

About Amarin

Amarin is a late-stage biopharmaceutical company with a focus on cardiovascular disease. The Company's lead product candidate is AMR101, a prescription grade Omega-3 fatty acid comprising not less than 96% ultra-pure ethyl eicosapentaenoic acid (EPA), which is entering Phase 3 clinical trials for the treatment of hypertriglyceridemia and mixed dyslipidemia under Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA). Amarin recently established its research and development headquarters in Mystic, Connecticut with an experienced research and development team. Amarin's programs capitalize on its lipid science expertise and the known therapeutic benefits of Omega-3 fatty acids in treating cardiovascular disease. The pipeline also includes proprietary next-generation lipid candidates, currently at preclinical stages of development.

Amarin has a range of clinical and preclinical stage compounds to treat central nervous system (CNS) disorders, including Huntington's disease, myasthenia gravis, Parkinson's disease and epilepsy, all of which are available for partnering. Amarin is listed in the U.S. on the NASDAQ Capital Market ("AMRN"). For more information please visit www.amarincorp.com.

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Disclosure Notice

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